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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO |
|-----------------------------------|---------------|----------------------|-------------------------|-----------------|
| 09/599,152 | 06/21/2000 | David J. Yang | UTXC:664 | 6919 |
| 759 | 90 10/28/2002 | | | |
| Teresa J Bowles | | | EXAMINER | |
| 600 Congress Avenue Suite 2400 | | | JONES, DAMERON LEVEST | |
| Austin, TX 787 | 701 | | ART UNIT PAPER NUMBER | |
| | | | 1616 | 13 |
| | | | DATE MAILED: 10/28/2002 | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) | | | | |
|---|--|--|--|--|--|--|
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| Office Action Summary | 09/599,152 | YANG ET AL. | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| The MAILING DATE of this communication and | D. L. Jones | 1616 | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status | | | | | | |
| 1) Responsive to communication(s) filed on 30 July 2002. | | | | | | |
| , | ☐ This action is FINAL . 2b)☐ This action is non-final. | | | | | |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | | |
| Disposition of Claims | | | | | | |
| 4)⊠ Claim(s) <u>2-41 and 52-55</u> is/are pending in the application. | | | | | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | |
| 6)⊠ Claim(s) <u>2-5 and 33-38</u> is/are rejected. | | | | | | |
| 7)⊠ Claim(s) <u>6-32,39-41 and 52-55</u> is/are objected | to. | | | | | |
| 8) Claim(s) are subject to restriction and/or election requirement. | | | | | | |
| Application Papers | | | | | | |
| 9) The specification is objected to by the Examiner. | | | | | | |
| 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner. | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | |
| 11) The proposed drawing correction filed on is: a) □ approved b) □ disapproved by the Examiner. | | | | | | |
| If approved, corrected drawings are required in reply to this Office action. 12)☐ The oath or declaration is objected to by the Examiner. | | | | | | |
| , | | | | | | |
| Priority under 35 U.S.C. §§ 119 and 120 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). | | | | | | |
| a) All b) Some * c) None of: | | | | | | |
| 1. Certified copies of the priority documents have been received. | | | | | | |
| 2. Certified copies of the priority documents have been received in Application No | | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage | | | | | | |
| application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application). | | | | | | |
| a) ☐ The translation of the foreign language provisional application has been received. 15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. | | | | | | |
| Attachment(s) | | | | | | |
| Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11 | 5) Notice of Informal | y (PTO-413) Paper No(s) Patent Application (PTO-152) | | | | |
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ACKNOWLEDGMENTS

1. The Examiner acknowledges Paper No. 12, filed 7/30/02, wherein the specification was amended; claims 9 and 22 were amended; claims 52-55 were added; and a declaration under 37 CFR 1.132 was submitted.

Note: Claims 2-41 and 52-55 are pending.

RESPONSE TO APPLICANT'S ARGUMENTS/AMENDMENT

2. The Applicant's arguments filed 7/30/02 (Paper No. 12) to the rejection of claims 3-5, 9-12, 15, 16, 18, 22, and 33-41 made by the Examiner under 35 USC 103 and/or 112 have been fully considered and deemed persuasive-in-part for the reasons set forth below.

(112 Rejections)

The 112, second paragraph, rejections are WITHDRAWN because Applicant has amended the claims to overcome the rejections.

(103 Rejections)

- I. The 103(a) rejections over Ilgan et al, Mangera et al, Zareneyrizi et al, and Yang et al is WITHDRAWN because Applicant's declaration filed under 37 CFR 1.132 is found persuasive.
- II. The rejection of claims 2, 3, 33, and 34 under 35 USC 103(a) as being unpatentable over Anderson et al (Nucl. Med. Biol., 1995, Vol. 22, No. 2, pages 165-173) is MAINTAINED for reasons of record in the Office Action mailed 4/24/02, Paper No. 10, and those set forth below. Likewise, the rejection of claims 2-5 and 33-38 under

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35 USC 103(a) as being unpatentable over Anderson et al (Nucl. Med. Biol., 1995, Vol. 22, No. 2, pages 165-173) in view of Marzilli et al (US Patent No. 5,986,074) or Bergstein et al (US Patent No. 5,279,811) is MAINTAINED for reasons of record in the Office Action mailed 4/24/02, Paper No. 10, and those set forth below.

Applicant asserts that Anderson et al only makes reference to the observation that an indium complex is desirable when designing bifunctional chelates to be conjugated to larger molecules. Thus, the reference does not identify EC conjugates, but suggest that the conjugates would be unpredictable when conjugated to proteins and peptides.

In the title and abstract of Anderson et al, EC is disclosed in combination with a radionuclide. In the abstract, it is disclosed that derivatives of a may have application as bifunctional chelates for 111In-labeled proteins and peptides and that 68-Ga-EC may have potential as myocardial PET imaging agents. Thus, a skilled practitioner in the art would be motivated to generate a method of radiolabeling a tissue specific EC ligand and a method of imaging using a tissue specific EC ligand complex based on the teachings of the reference. Furthermore, the abstract discloses that the stability of In-EC was greater than Ga-EC which does not mean that the complexes are so unstable until they are not useful in vivo. Thus, a skilled practitioner in the art would be motivated to use the complexes in vivo and modify them as necessary for their desired purposes.

Applicant is correct in the assertion that Tc-EC complexes are known in the art. For evidence of such teachings see for example, Marzilli et al, column 4, line 40.

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CLAIM OBJECTIONS

3. Claims 6-32, 39-41, and 52-55 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Note: The claims are distinguished over the prior art of record because the prior art neither anticipates nor renders obvious the specific ligands as set forth in the claims.

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (703) 308-4640. The examiner can normally be reached on Mon.-Fri. (alternate Mon.), 6:45 a.m. - 4:15 p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose' Dees can be reached on (703) 308- 4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

D. L. Johes

Primary Examiner Art Unit 1616

October 25, 2002